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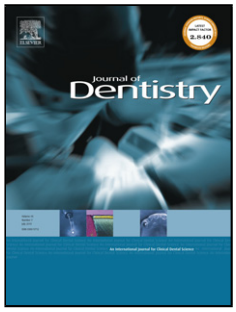

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Randomized Clinical Trial on the Survival of Lithium Disilicate Posterior Partial restorations Bonded Using Immediate or Delayed Dentin Sealing After 3 Years of Function

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Running title: Immediate and delayed dentin sealing effect on survival of partial restorations

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SUMMARY

Objectives The survival and success rate and the quality of survival of partial ceramic restorations bonded employing Immediate (IDS) or Delayed Dentin Sealing (DDS) in vital molar teeth were evaluated in a randomized clinical trial with within-subject comparison study.

Materials and Methods 30 patients received two lithium disilicate ceramic (IPS-e.max press, Ivoclar Vivadent) partial restorations on vital first or second molar teeth (N=60). The two teeth randomly received either IDS (test group, n=30) or DDS (control group, n=30). Partial ceramic restorations were luted (Variolink Ultra, Ivoclar Vivadent) two weeks after preparation. Evaluations were performed at 1 week, 12 months and 36 months post-operatively, using qualitative (FDI) criteria. Representative failures were evaluated microscopically (SEM) and by means of simplified qualitative fractography analysis.

Results One absolute failure occurred in the DDS group due to (secondary) caries. The overall survival rate according to Kaplan-Meier after 3 years was 98.3% (FDI criteria score 1-4, n=59) and the overall success rate was 85% (FDI criteria score 1-3, n=51), with no significant difference between restorations in the IDS and DDS group (p=0.32; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%). For the quality of the survival, no statistically significant differences were found between IDS and DDS (p=0.7; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%) restorations on any follow-up timepoints for any of the FDI criteria (Wilcoxon, McNemar, p>0.05)..

Conclusion Adhesively luted partial ceramic restorations in vital molar teeth have a good prognosis, however IDS did not show any differences in success and survival rates after 3 years of function.

Key words: Adhesion, Immediate Dentin Sealing, Lithium Disilicate, Randomized Clinical Trial, Partial Restorations, Survival

INTRODUCTION

When anatomy of biomechanically or aesthetically compromised teeth could not be restored by means of a direct restoration they can be restored with partial ceramic indirect restorations. Due to advances in adhesive technologies and ceramic materials it is possible to restore teeth at a limited biological price saving sound tooth tissue. The longevity of these partial ceramic restorations relies heavily on the adhesive strength of the resin luting cement to the ceramic restoration and to the tooth surface but also on the ceramic material that is used.

Currently numerous ceramic materials are available for fabricating indirect partial restorations. [1,2] Glass ceramics comprise a vitreous and crystalline phase in which a glassy matrix could be etched optimizing the adhesive bonding strength of these materials. [3-5] In contrast, crystalline ceramics, alumina and zirconia, have minimal or practically no vitreous phase. [3,5] These materials differ in mechanical properties which raises the question what material is best suited for the heavily loaded posterior region. A recent meta-analysis on this subject [3] indicated that the type of ceramic material (feldspathic porcelain vs. glass-ceramic), study design (retrospective vs. prospective), follow-up time (5 vs. 10 years), and study setting (university vs. private clinic) did not affect the survival rate. Estimated survival rates for glass-ceramics and feldspathic porcelain varies between 92% and 95% at 5 years and 91% at 10

years. [3] Failures were related to fractures (4%), endodontic complications (3%), secondary caries (1%) and debonding (1%). [3] However, long-term data comparing survival and success of various types of all-ceramic crowns are lacking. [6]

Adhesion to dentin in particular remains a clinical challenge in clinical dentistry to date. Immediate Dentin Sealing (IDS) has been suggested as an alternative to conventional adhesive luting, also referred to as Delayed Dentin Sealing (DDS). [7-13] With IDS, a thin layer of adhesive resin is applied immediately after tooth preparation and prior to impression taking, whereas with DDS, the adhesive resin layer is applied just before luting the restoration. IDS has been extensively studied and significantly improved over the years with positive results with respect to bond strength, gap formations, bacterial leakage, and post-cementation hypersensitivity. [7-10,13-22] However, randomized controlled trials on IDS need to be performed, and consequently it is unknown if IDS is a beneficial procedure, preventing failures

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n partial indirect restorations. [14]

Therefore, the objective of this study is to evaluate the survival and success rate and the quality of survival of lithium disilicate posterior partial restorations bonded using immediate or delayed dentin sealing after 3 years of function. The tested null hypotheses were that there would be no significant differences in success and survival rate and the quality of survival between partial indirect ceramic restorations bonded with either IDS or DDS.

METHODS AND MATERIALS

Study Design

Between December 2013 and May 2016, a total of 30 patients (13 women, 17 men; mean age: 54 years) with an indication for two indirect partial ceramic restorations on first or second vital molar teeth were recruited. The inclusion criteria were the following: physically and psychologically able to tolerate conventional restorative procedures; good oral hygiene; presence of intact buccal wall of the tooth; normal response on cold test; possibility to apply rubber dam; presence of the antagonistic tooth; and willingness of the patient to return for follow-up examinations. Response on cold test was tested using a coolant spray

(Külte spray, Orbis Dental, Münster, Germany) on a cotton ball (4 mm) that was applied directly to the buccal wall of the corresponding tooth and it was recorded when the patient responded or not.

The two teeth randomly received either IDS (test group, n=30) or DDS (control group, n=30) through randomization software (www.randomizer.org). Hence, the study can be characterized as a randomized controlled, single blind clinical trial with within-subject comparison. A consort flow chart showing the enrollment, intervention allocation, follow-up, and data analysis is presented in Figure 1. The study was approved by the Medical Ethics Committee of the University Medical Center Groningen, The Netherlands (ABR number: NL 45130) and registered in the Clinical Trial Register of the US National Library of Medicine (NCT03443583). All patients were provided with informed consent. Distribution of restorations and extension of the restorations are presented in Table 1.

Tooth preparation

The brands, types, manufacturers, chemical compositions and batch numbers of the main materials used in this study are listed in Table 2. After isolating the teeth with rubber dam (Hygenic Dental dam, Coltène/Whaledent Inc., Ohio, USA) the existing restorations were removed. Undergraduate students executed tooth preparation and luting of the restoration in their first, second or third year of their dentistry masters' closely supervised by one dentist and following the procedure described as part of a documented clinical protocol. The outline configuration was a butt shoulder, prepared using diamond burs and specific inserts for inlay preparations in an ultrasonic handpiece (SONICflex prep ceram, KaVo GmbH, Biberach/Riss, Germany). All internal angles were smoothened to reduce stress concentration. The cusps were covered (1.5 mm) if the remaining tooth structure wall was less than 2 mm thick from its occlusal aspect or when the outline of the restoration would be in an area with static or dynamic antagonist contacts. With proximal cavities, slight divergence with an angle of 100 to 120° between the proximal cavity walls and the prospective proximal inlay surfaces were provided. The dental technician blocked out any incidental undercuts in the teeth that were allocated to the control group (DDS), the remaining cases were compensated for by the IDS.

The teeth on the test group received IDS (Clearfil SE Primer and Adhesive, Clearfil Majesty Flow, Kuraray) immediately after exposure of dentin (table 3a). Electrosurgery was performed in cases where retraction of the gingiva was required for proper impression making. Impressions were made using a silicone impression material (Heavy and Ultra Light body Aquasil, Dentsply, Mildford, USA) using an individually made acrylic impression tray. Temporary restorations were then made chair-side using a chemically polymerized resin material (Protemp, 3M ESPE, Neuss, Germany) and cemented using polycarboxylate cement (Durelon, 3M ESPE, Minn, USA).

Luting

One dental technician fabricated all lithium disilicate restorations (IPS e.max press, Ivoclar Vivadent, Schaan, Liechtenstein) following manufacturer instructions. Restorations were glazed at low temperatures applied to the restoration after construction (FLUO IPS e.max Ceram Glaze paster, Ivoclar Vivadent). Two weeks after preparation, the temporary cement was removed from the teeth with an ultrasonic tip and a scaler. The sequence of the different tooth conditioning and restoration procedures, before luting are presented in Tables 3a-b and 4. The adhesive procedure differed between the test and control group, as outlined in these tables. All the partial restorations were luted using a heated (55°C; RØNVIG A/S, Daugaard, Denmark) dual-polymerized luting composite (Variolink Ultra, Ivoclar Vivadent). Restorations were placed initially under slight pressure where the excess material was removed immediately from the margins with a probe, a scaler and waxed dental floss (Jonhson&Johnson, Sezanne, France). After increasing the pressure, the final excess composite was manipulated against the tooth in order to prevent marginal gaps. The restorations were photo-polymerized (>1.000 mW/cm^2, 11000mWs/cm^2, Bluephase Style, Ivoclar Vivadent) for 40 seconds from 3 sides and this was repeated after the application of glycerin gel (K-Y Johnson & Johnson, Sezanne, France). Occlusion and articulation was checked carefully using a 40-μm carbon paper (Bausch, Cologne, Germany). The margins of the restorations were finished using a scaler and an ultrasonic device (EVA-handpiece 7LP in combination with a 61 LG, KaVo GmbH) and polished using ceramic polishers (CeraGloss

blue and yellow, Edenta, Argau, Switzerland). Intra-oral radiograph was then made in order to check for excess composite in the cervico-approximal region.

Evaluation

Restorations were evaluated at baseline (1 week after luting of the restorations) and thereafter at 12 months and 36 months. One observer evaluated the restorations according to the FDI criteria [23] calibrated by the e-calib web-based training (www.e-calib.info). The FDI criteria are used to measure the quality of survival and determining the success or survival of a restoration. Restorations without any major adverse effects scored 1-3 on FDI criteria and were considered as a success. Restorations with a score 4 on any of the FDI criteria were considered repairable failures and considered to have survived. Restorations with a score 5 on FDI criteria were non-reparable failures and were considered as absolute failures. The proximal contact points were checked by passing waxed dental floss (Jonhson&Johnson, Sezanne) through the interdental space. Restorations were visually (2.3x magnification loops, Examvision, Rotterdam, The Netherlands) inspected with a dental mirror and probe. Patients were instructed to call if any kind of failure occurred. Digital photographs (1:1) and intra-oral radiographs were made after placement of the restorations and during follow-up sessions.

FEG-SEM (Scanning Electron Microscopy)

In case of any failure, an impression (Ultra Light and Heavy body Aquasil, Dentsply, Mildford, USA) was made from the failure site after cleansing the surface with absorbent paper and sodium hypochlorite 0.5%. Impressions were poured with cold mounting epoxy resin (EpoxyCure2, Buehler, IL, USA). After final curing, the replicas were sputter-coated with a 3 nm thick layer of gold (80%) / palladium (20%) (90 s, 45mA; Balzers SCD 030, Balzers, Liechtenstein) and analysed using a dual beam FEG-SEM/FIB microscope

(LyraTESCAN, Brno, Czech Republic). The evaluation focused on marginal and surface integrity-homogeneity and continuity along bonding interface and ceramic surface.

Statistical Analysis

Statistical analysis was performed using SPSS 22.0 software for Windows (SPSS Inc., Chicago, IL, USA). Data were analyzed using Kaplan-Meier (Log Rank (Mantel-Cox)) tests to obtain the overall success and survival rates in relation to observation time, and Wilcoxon test and McNemar test were used to test differences in the overall quality of survival. The alpha level was set at 0.05 in all tests.

RESULTS

After 36 months no dropouts were experienced, 60 indirect posterior restorations (IDS, n = 30; DDS, n = 30) were evaluated. Mean observation time was 37.6 months (SD 2.9 months, min. 32 months, max. 43 months). Seventeen men and 13 women were included. The distribution of the location of the restorations is overviewed in table 1.

The overall survival rate (FDI criteria score 1-4, n=59) is 98.3% after 36 months (figure 5). The survival rates for IDS and DDS were 100% and 96.7% respectively (not significantly different, p=0.32; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%).

Following FDI criteria score 4 (table 5) relative failures occurred in the DDS group (n=4; chipping n=2, fracture n=1 and periodontal complications n=1). Considering relative failures in the DDS group; tooth and restoration chipping with dentin exposure after 36 months was seen in a patient with severe teeth grinding, the other chipping failure was a small fragment on an occlusal buccal cusp. The fracture (figure 2) originated after 36 months on a bearing cusp and part of the restoration. It could be repaired with a composite material. Qualitative fractography analysis was possible to this sample showing a critical flaw (probable site of failure initiation).

Following FDI criteria score 4 (table 5) relative failures occurred in the IDS group (n=4; debonding n=1, excessive wear n=1, secondary caries n=1 and periodontal complications n=1). Considering relative failures in the IDS group; the debonding failure was a complete adhesive failure between the luting agent and the restoration and occurred 14 months after luting (figure 3). After cleaning the luting surface and removing the composite from the

restoration surface, the restoration was replaced using the same adhesive protocol. Excessive wear was seen in a patient with severe teeth grinding (figure 4). Both periodontal complications (IDS and DDS) occurred in the same patient.

One absolute failure had occurred in the DDS group (secondary caries). The secondary caries developed in a medically compromised patient whose oral hygiene had seriously deteriorated, resulting in deep caries, imposing the prognosis of this tooth.

The overall success rate (FDI criteria score 1-3, restorations without any adverse effects, n=51) after 36 months is 85% (figure 6), not different for the IDS and DDS group (86.7% versus 83.3%, p=0.7; Kaplan-Meier, Log Rank (Mantel-Cox), CI=95%).

Considering FDI criteria, restorations scored a duller surface after 36 months compared to 1 week. Some patients (n=5) experienced ~~some~~ postoperative sensitivity after 1 week, but this had resolved at 12 months. No patients reported tooth hypersensitivity after 36 months. No statistically significant differences were found between IDS and DDS restorations on any follow-up timepoints for any of the FDI criteria (Wilcoxon, McNemar, p>0.05).

Patients did not call or come in for any kind of failure (except for the debonding). All failures were noted at the planned follow-up moments.

DISCUSSION

In this clinical trial the performance of partial ceramic restorations bonded employing Immediate (IDS) or Delayed Dentin Sealing (DDS) in the same patient were compared. Based on non-significant differences in the success and survival rates and the quality of survival with IDS and DDS, the null hypothesis could not be rejected. The results cover up a period of 36 months. All absolute and relative failures were left unnoticed by the patient (except for the debonding), hence were observed at the scheduled recall visit. Consequently, the exact time of occurrence could not be registered.

A possible shortcoming of this study is that students executed the treatments and that the population was not very homogenous in terms of oral hygiene. However given the small differences we found between the groups, we argue that even with a considerable increase in sample size the likelihood that we would have found a clinically

relevant difference is very small. The number of absolute failures was limited; one restoration presented with secondary caries and had to be extracted. Two patients showed very poor oral hygiene despite regular adjustments during dental-checks ups every 6 months, this resulted in caries during follow-up. One tooth with secondary caries resulted in a relative failure and the other in an absolute failure. Depending on the location and the accessibility of the cavity caries results in an absolute or a relative failure. [24] Secondary caries develops mainly on the proximal gingival floor of class II restorations, usually being independent of the restorative material. [25-27]

Two relative failures occurred in one patient with severe teeth grinding. He reported not to have used the provided splint at night. The cohesive strength of ceramics proved insufficient for this (and possibly also others) individuals with parafunctional habits [28] and thus a splint is indicated for such patients but also the restoration design is of great importance. One failure in this patient being excessive wear and one being tooth chipping (figure 4). A possible explanation for the occurrence of tooth chipping is that the preparation design had not been uniform. The thickness of the ceramic was not similar all over the tooth, leading to a variation in wall height and resulting in a higher stress concentration. [29] This is also considered a probable cause of failure in figure 2 because the SEM image shows an abrupt geometry and thickness variation; dimensional volumetric transitions, from thicker to thinner areas, should not occur in very small distances in brittle materials. This results in an unfavorable stress distribution that could create a fracture initiation site. [30-32] In both failures in the patient with severe teeth grinding a fracture line is seen in the ceramic (figure 4) and received a score 3 for FDI criteria on fracture of material and retention. Cracks are acceptable as long as there are no clinical symptoms present. [24] A small fracture in the ceramic is not always a problem as long as the location and adhesive is supportive and thus the stress can be distributed enough to prevent the restoration from catastrophic failure. [33] Especially in patients with severe teeth grinding, compromised design of the restoration or preparation is less forgiving. One of the relative failures was due to a fracture (figure 2). Here, the stress distribution may lead to a problem due to design of the restoration (thin isthmus). Because the mesio-lingual cusp was left too high and too thin, cuspal deflection may have lead to the fracture. Cuspal coverage is commonly recommended in order to protect the weakened tooth structure. [34] The benefit of a full cuspal coverage design (onlay) can be explained by the amount of the remaining tooth structure [35], resulting in favorable distribution of stresses in teeth and reduces risk of fracture. [36] The discolored part of the wall indicates leakage of the restoration, probably due to cuspal deflection the bonding disrupted in this part. Preparation margins should have correct configuration to prevent chippings and cracks from and in the ceramic leading to crack propagation. [32] Fracture initiation sides are often created by parts in the

restoration where the ceramic is very thin or where there is an air bubble present in the ceramic material. [29,32] Avoiding marginal ridge contact is recommended for these kind of restorations. In partial ceramic restorations IDS is thought to improve the adhesion resulting in improvement of the fracture strength. [37] Although we did not find any statistically significant difference in the performance of partial restorations using IDS or DDS some failures only occurred in the DDS group; tooth chipping and fractures. When using IDS with indirect bonded restorations, the delayed placement of the restorations and postponed occlusal loading facilitates the dentin bond to develop without stress. [38] The use of IDS may have lead to less fractures and chipping in this study but further follow-up is needed to support the in vitro results and to see if IDS could indeed prevent some failures in partial indirect restorations on the mid- and long-term analysis.

In the debonding failure after 14 months (figure 3), the disto-buccal part of the restoration showed a discolored part which could indicate that there was not enough luting agent at this site of the restoration resulting in insufficient marginal sealing. Early failures are commonly related to technical flaws and not as a consequence of fatigue. During luting of this restoration, the cement was already partly light-cured by environment light, compromising the initial fit of the restoration. This part of the cement had to be removed and the procedure had to be redone. The procedure for ceramic bonding remains technique sensitive. [39] Factors that complicate ceramic bonding include cement manipulation and adherence to bonding protocol, moisture control and etching. [40] This is even more important with partial ceramic restorations where preparation are non retentive and fully rely on the adhesive bonding to retain the restoration.

Two periodontal failures were in a single patient as a result of poor oral hygiene during the follow-up period and to lack of regular dental check-ups. Following FDI criteria a periodontal failure with score 4 (relative failure) is scored when there is a difference of more than one grade of probing and bleeding index worsening in comparison to control tooth or when there is an increase in pocket depth of more than 1 mm. The increased pocket depths are not likely to have high impact on the longevity of the restoration itself, but rather reflects the functional oral environment. The restorations of this patient were not in direct contact with the periodontal tissues.

The survival rate of the restorations in this study (98.3%) is comparable to that in other studies but the success rate (85%) is somewhat lower than reported elsewhere. [3] The former may reflect the (initially limited) experience of the team in providing this type of restorations as training and experience is presumed to affect the outcome. No endodontic complications were seen while this is a common failure in other studies (3%). [3] This finding reflects the minimal invasive preparation design as the amount of tooth structure reduction is considered to be an important factor affecting postoperative tooth sensitivity. [35] A polycarboxylate cement was used for cementation of the temporary restorations. This cement is known for its bond capacity to enamel and dentin, low irritancy and antibacterial action. The zinc-polycarboxylate cements have been found to have some anti-bacterial properties due to its adhesive quality, which means that a better barrier to the ingress of bacteria is provided than by other zinc-phosphate cements. [41] This can therefore have ensured a very well seal of the temporary restoration also in the DDS group were the dentin was not covered directly after preparation. Which may also have contributed to less bacterial invasion and resulting in less postoperative problems.

Clinically it is difficult, to differentiate between gaps at the interface between luting material and hard tissues, and between luting material and restoration in compromised restorations. SEM examination was considered quite useful in assessing these aspects and is recommended for other clinical survival studies as well.

CONCLUSIONS

Adhesively luted partial ceramic restorations in vital molar teeth have a good prognosis. No significant differences in success and survival rates after 3 years of function were found between IDS and DDS,

Conflict of interest

The authors' institutions supported this study. The authors declare that they have no conflicts of interest and that they did not have any commercial interest in any of the materials used in this study.

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Captions to the tables and figures:

Figures:

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram explaining enrollment, intervention allocation, follow-up and data analysis.

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

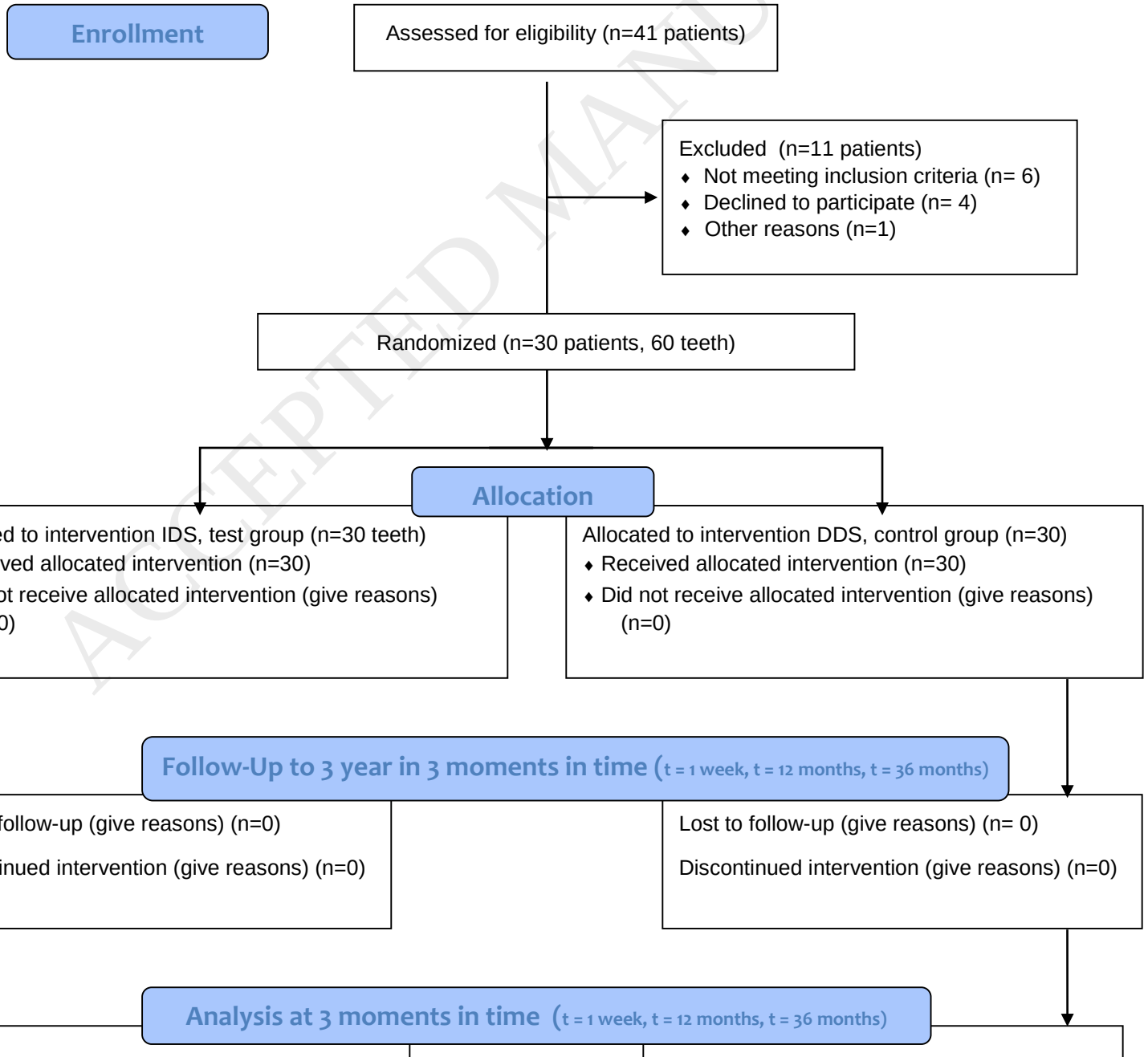


Figure 2a-d. a) Restoration on tooth 36 (DDS group) after 12 months in situ. Note the fracture line at the mesio-lingual cusp. **b)** Fracture of the mesio-lingual aspect of the restoration after 36 months in situ. Note the discolored dentin part at the inner wall next to a remnant of composite material. **c)** SEM image of the occlusal view after fracture of the restoration after 36 months. **d)**

Qualitative fractography on SEM image of ceramic fracture surface showing a critical flaw (probably site of failure initiation). Note the mirror region beneath the critical flaw.

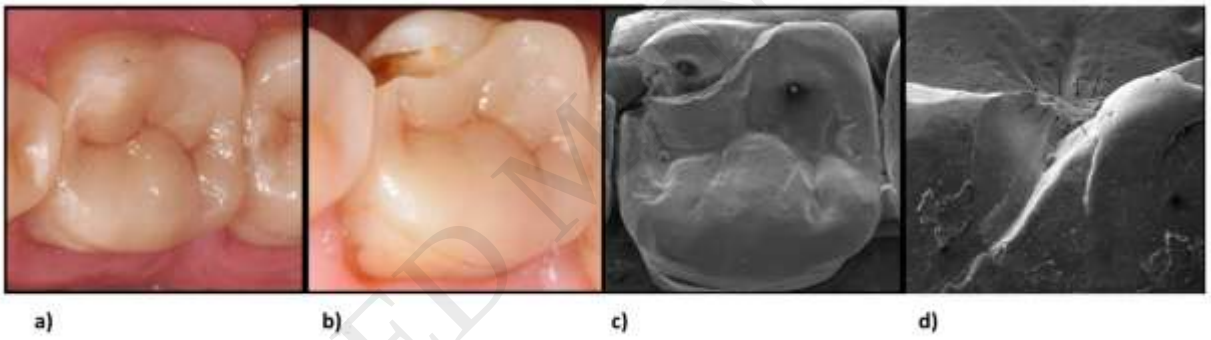


Figure 3 (left) Tooth surface after debonding of restoration 36, note the intact IDS/composite layer on the tooth. **(right)** Restoration debonding surface. Note the resin composite at the intaglio surface and the discolored disto-buccal part of the restoration.

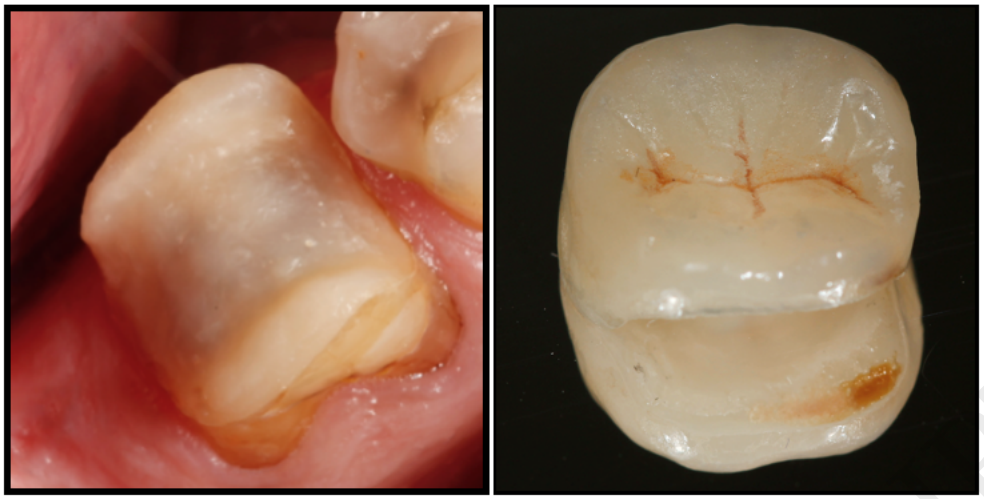


Figure 4 (left) Excessive wear on the occlusal part of the restoration 26 after 36 months. Note the fracture line in the ceramic on the buccal side of the restoration. **(middle)** SEM image of restoration 26. Note the excessive wear and the clear fracture line in the ceramic from mesial to distal. **(right)** Detailed SEM image of small bending and branching of the fracture line in the ceramic.

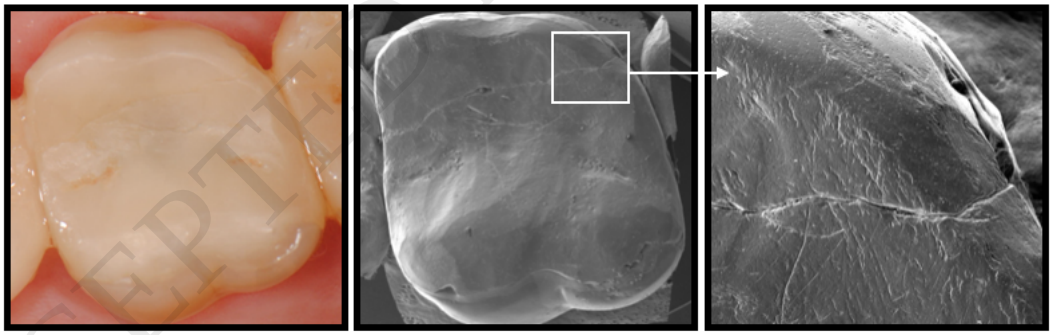


Figure 5 Kaplan-Meier curve of the survival rate of partial ceramic restorations bonded employing either Immediate (IDS) or Delayed Dentin Sealing (DDS) (IDS: 100%, n = 30; DDS: 96.7%, n = 30, events n = 1).'

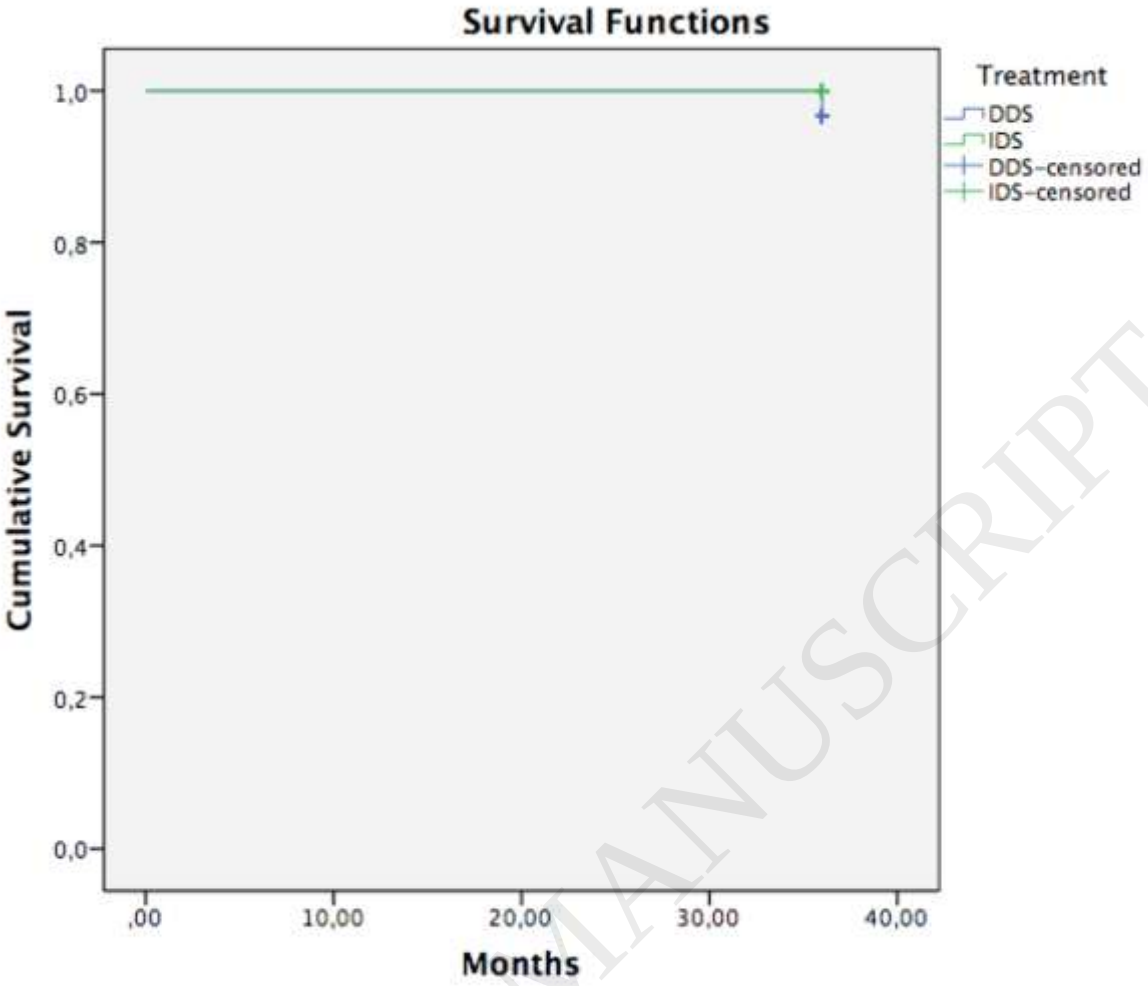
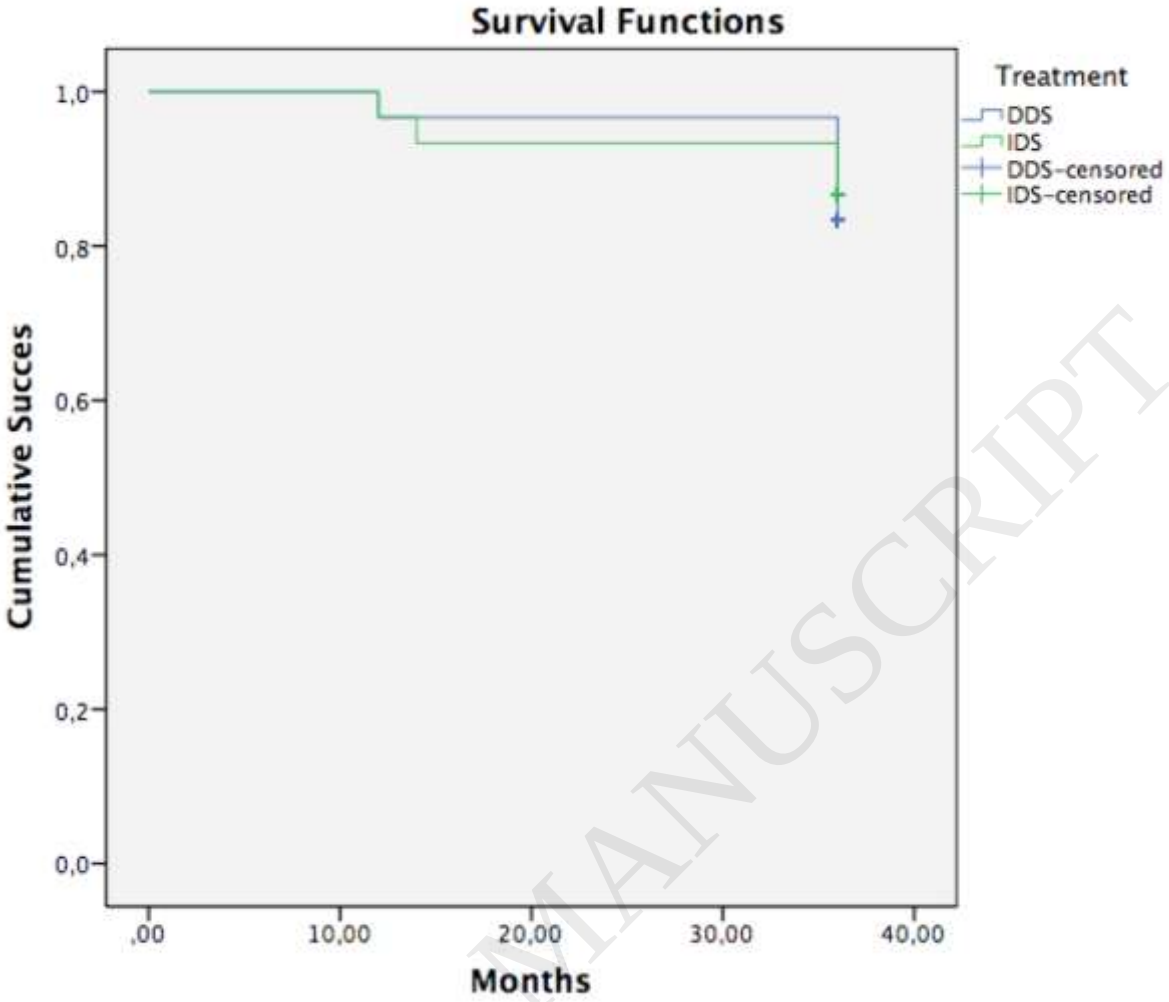


Figure 6 Kaplan-Meier curve of the success rate of partial ceramic restorations bonded employing either Immediate (IDS) or Delayed Dentin Sealing (DDS) (IDS: 86.7%, n = 30, events n= 4; DDS: 83.3%, n = 30, events n = 5).



Tables:

Table 1 Distribution of restored teeth and extension of the restorations in the maxilla and mandible in the test (Immediate Dentin Sealing-IDS) and control (Delayed Dentin Sealing-DDS) group.

Test group	**Molars (n)**					**Total (N)**
	0 cusps replaced	**1 cusp replaced**	**2 cusps replaced**	**3 cusps replaced**	**4 cusps replaced**	
Maxilla (n)	2	4	5	2	6	19
Mandible (n)	2	1	1	4	3	11
Total (N)	4	5	6	6	9	30

Control group	**Molars (n)**					**Total (N)**
	0 cusps replaced	**1 cusp replaced**	**2 cusps replaced**	**3 cusps replaced**	**4 cusps replaced**	
Maxilla (n)	5	1	1	2	5	14
Mandible (n)	2	3	5	2	4	16
Total (N)	7	4	6	4	9	30

Table 2 The brands, types, manufacturers, chemical compositions and batch numbers of the major materials used in this study.

Table 2. The brands, types, manufacturers, chemical compositions and batch numbers of the major materials used in this study.

Brand	Type	Manufacturer	Chemical composition	Batch-number
IPS-e.max Press	Pressable ceramic	Ivoclar Vivadent, Schaan, Liechtenstein	SiO_2, LiO, K_2O, P_2O_5, ZrO_2, ZnO.	-
Variolink Ultra Catalyst / Base	Dual-cure luting composite	Ivoclar Vivadent	Ytterbium trifluoride, Bis-GMA, urethane dimethacrylate, 4 triethylene glycol dimethacrylate, dibenzonyl peroxide, titanium dioxide	S27220/ S0664
Clearfil SE Primer	Adhesive primer	Kuraray CO., Ltd., Osaka, Japan	HEMA, hydrophilic dimethacrylate, water, photo-initiator	2U0022
Clearfil SE Bond	Adhesive resin	Kuraray CO., Ltd.	MDP, HEMA, bis-GMA, hydrophilic dimethacrylate, water, photo-initiator, silanated colloidal silica	2T003
Excite F DSC	Single component adhesive	Ivoclar Vivadent	Phosphonic acid acrylate, dimethacrylates, hydroxyethyl methacrylate, highly dispersed silicon dioxide, ethanol catalysts, stabilizers, fluoride	S36470
CoJet-sand	Blast-coating agent	3M ESPE, Minn, USA	Aluminium trioxide particles Coated with silica, 30 µm	446317/ 534151

ESPE-Sil	Silane coupling agent	3M ESPE	Ethyl alcohol, 3-methacryloxypropyl-2 trimethoxysilane, ethanol	51827
Monobond Plus	One component primer	Ivoclar Vivadent	Ethanol, 3-trimethoxysilsylpropyl-methacrylate, methacrylated phosphoric acid ester	S31153
IPS Ceramic etch	Hydrofluoric acid	Ivoclar Vivadent	<5% Hydrofluoric acid powder	
S26140 IPS Neutralizing powder Vivadent	Sodium carbonate	S34285 Ultra-etch	35% Phosporic acid 35% phosphoric acid	Ivoclar
130910 Clearfil Majesty Flow	Ultradent, South Jordan UT, USA		Photo-cure composite	
Kuraray CO.	Triethylene glycol dimethacrylate, Hydrophobic aromatic dimethacrylate, Silanated barium glass filler, Silanated silica filler, dl-Camphorquinone			00339BA
Glycerin gel	K-Y* lubricating gel	K-Y, Johnson & Johnson, Sezanne, France	Purified water, Glycerin, Methylparaben, Propylparaben, Propylene Glycol, Hydroxyethylcellulose, Dissodium, Phosphate, Sodium Phosphate, Tetrasodium, EDTA	1233V

Table 3a-b Clinical protocol for the **a)** test group (Immediate Dentin Sealing-IDS), **b)** control group (Delayed Dentin Sealing-DDS).

Visit 1: Tooth Preparation	Working time (s)
1.1 Tooth preparation	
1.2 Apply Clearfil SE Primer, active brushing motion	20
1.3 Air suction	
1.4 Apply Clearfil SE Adhesive, active brushing motion	10
1.5 Air-thin	10
1.6 Photo-polymerize	10
1.7 Apply flowable resin (Clearfil Majesty flow)	
1.8 Photo-polymerize	40
1.9 Apply glycerin gel	
1.10 Photo-polymerize at buccal, oral and proximal sites	40 each
1.11 Rinse until clean surface	
1.12 Clean the enamel outline with a rubber-point or a bur	
1.13 Make impression	
Visit 2: Cleaning and conditioning of the tooth prior to luting	
2.1 Clean tooth surface (EMS)	
2.2 Silica-coat (CoJet-sand) the IDS	2-3
2.3 Acid etch enamel	30
2.4 Rinse	30
2.5 Dry	
2.6 Apply silane (ESPE-sil) on the IDS	60
2.7 Apply adhesive resin (Excite F DSC)	

2.8 Apply resin cement (Variolink Ultra) on the tooth	
2.9 Place the partial restoration on the tooth	
2.10 Remove excess cement	
2.11 Photo-polymerize at buccal, oral and proximal sites	40 each
2.12 Apply glycerin gel	
2.13 Photo-polymerize at buccal, oral and proximal sites	40 each

Visit 1: Tooth Preparation	Working time (s)
1.14 Tooth preparation	
1.15 Make impression	

Visit 2: Cleaning and conditioning of the tooth prior to luting

2.1 Clean tooth surface (EMS)	
2.2 Acid etch enamel and dentin	30
2.3 Rinse	30
2.4 Dry	
2.5 Apply adhesive resin (Excite F DSC)	
2.6 Apply resin cement (Variolink Ultra) on the tooth	
2.7 Place the partial restoration on the tooth	
2.8 Remove excess cement	
2.9 Photo-polymerize at buccal, oral and proximal sites	40 each
2.10 Apply glycerin gel	
2.11 Photo-polymerize at buccal, oral and proximal sites	40 each

Table 4 Clinical protocol for luting procedures of the ceramic restorations.

Visit 2: Luting procedures of the ceramic restorations	Working time (s)
2.1 Apply hydrofluoric acid etch (IPS ceramic etch)	20
2.2 Rinse and neutralize	60
2.3 Rinse and dry	
2.4 Ultrasonically clean in distilled water	300
2.5 Dry	
2.6 Apply silane (Monobond plus) one coat and wait its reaction	60
2.7 Apply adhesive resin (Excite F DSC)	
2.8 For the subsequent procedures, follow step 2.8 in Table 3a or step 2.6 in Table 3b.	

Table 5. Summary of the FDI criteria evaluation at 1 week, at 12 months and at 36 months. Restorations with FDI score 1-3 are considered to have succeed. Restorations with FDI score 4 are considered to have relatively failed and are considered to have survived. Restorations with FDI score 5 are considered to have absolutely failed.

		IDS			DDS		
FDI criteria		1 week	12 months	36 months	1 week	12 months	36 months
A. Esthetic Properties							
1. Surface lustre	1	29	13	9	29	9	7

	2	1	10	14	1	11	13
	3	-	7	7	-	10	10
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
2. Staining surface / margin	1	30	28	21	30	27	21
	2	-	1	7	-	2	8
	3	-	1	2	-	1	1
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
3. Color match and translucency	1	24	21	20	28	26	23
	2	5	5	6	1	1	4
	3	1	4	4	1	3	3
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
4. Esthetic anatomical form	1	30	30	30	30	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
B. Functional properties							
5. Fracture of material and retention	1	28	26	26	30	29	26
	2	2	2	-	-	-	2
	3	-	2	4	-	1	1
	4	-	-	-	-	-	3
	5	-	-	-	-	-	-
6. Marginal adaptation	1	26	23	17	28	20	16
	2	3	7	12	2	9	13
	3	1	-	1	-	1	1
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
7. Occlusal contour wear qualatitively / quantitatively	1	30	29	28	30	29	29
	2	-	-	1	-	-	-
	3	-	1	-	-	1	1
	4	-	-	1	-	-	-
	5	-	-	-	-	-	-
8. Approximal anatomical form contact point / contour	1	30	30	30	30	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
9. Radiographic examination	1	29	29	28	28	29	29

	2	1	1	2	2	1	1
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
10. Patient's view	1	25	30	30	26	30	29
	2	-	-	-	-	-	-
	3	5	-	-	4	-	-
	4	-	-	-	-	-	1
	5	-	-	-	-	-	-
C. Biological properties							
11. Postoperative (hyper-)sensitivity and tooth vitality	1	28	30	30	27	30	30
	2	1	-	-	3	-	-
	3	1	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
12. Recurrence of caries, erosion, abfraction	1	30	30	28	30	30	27
	2	-	-	-	-	-	1
	3	-	-	1	-	-	1
	4	-	-	1	-	-	-
	5	-	-	-	-	-	1
13. Tooth integrity (enamel cracks, tooth fractures)	1	29	30	30	30	29	28
	2	1	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	1	2
	5	-	-	-	-	-	-
14. Periodontal response (compared to a reference tooth)	1	18	19	18	20	19	16
	2	12	7	9	0	8	12
	3	-	3	3	-	2	2
	4	-	1	-	-	1	-
	5	-	-	-	-	-	-
15. Adjacent mucosa	1	23	30	28	26	30	30
	2	7	-	2	4	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-
	5	-	-	-	-	-	-
16. Oral and general health	1	30	30	30	30	30	30
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
	4	-	-	-	-	-	-

5	-	-	-	-	-	-	-	-